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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,563	04/11/2001	Jack V. Smith	/ 7743	
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JACK V. SMITH			EXAMINER	
P.O. BOX 156 Arden, NC 28			BAKER, MAURIE GARCIA	
			ART UNIT	PAPER NUMBER
			1639	, ,
			DATE MAILED: 05/02/2003	Į į

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES DEPARTMENT OF COMMERCE **Patent and Trademark Office** COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICAN	IT ATTORNEY DOCKET NO.
09/829,563	04/11/01	SMITH	
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EXAMINER Maurie Garcia Baker, Ph.D. ART UNIT PAPER NUMBER 1639

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application Commissioner of Patents

Please see attached Notice of Non-Responsive Amendment.

DETAILED ACTION

Please note: The number of Art Unit 1627 has been changed to 1639. Please direct all correspondence for this case to Art Unit 1639.

- 1. An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed.

 Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.
- 2. Applicant is advised of the availability of the publication "Attorneys and Agents Registered to Practice Before the U.S. Patent and Trademark Office." This publication is for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Notice of Non-Responsive Amendment

3. The amendment filed on February 5, 2003 canceling all claims drawn to the elected invention and presenting only claims drawn to a non-elected invention is non-responsive (MPEP § 821.03). The remaining claims are not readable on the elected (i.e. previously examined) invention for the following reasons.

Art Unit: 1639

4. Applicant *originally* claimed a "method for determining an analyte of interest using nucleounits targeted to said analyte of interest". This method had steps of "identifying a nucleounit from a mixture of synthetic random sequences of nucleounit libraries", contacting the analyte with said mixture, removing the unbound nucleounits by partitioning, amplifying the remaining nucleounits by PCR, conjugating the nucleounits to an indicator and then using the conjugate for detecting the analyte of interest.

- 5. Applicant *now* claims methods "for the detection of Prostate Specific Antigen" that contain *none* of the above-mentioned steps. Newly added independent claim 8 has steps of "preparing a dry chemistry test means", drying such means and dipping it into the sample to detect the analyte via a color response. Newly added independent claim 12 has steps of using a "chemistry autoanalyzer" with various transferring, aliquoting and incubating steps, and detection by absorbance at certain wavelengths.
- 6. The newly added claims (i.e. 8-15) and the previously examined claims (i.e. 1-7) represent different methods. The methods are different because they use different steps, reagents and/or will produce different results/products. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, the methods use *completely different steps and reagents* as described above. Therefore, the inventions each have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified inventions respectively would not

necessarily anticipate or render obvious the other invention, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each invention could support a separate patent. The different inventions would require different searches in the patent and non-patent databases, and there is no expectation that the searches would be coextensive.

- 7. Moreover, the two new methods (i.e. newly added independent claim 8 and newly added independent claim 12) are different from each other for the same reasons. Use of "a dry chemistry test means" is different than using a "chemistry autoanalyzer". Thus, the newly added claims represent two distinct inventions, which are, in turn, both different from the invention previously claimed and examined.
- 8. The examiner recognizes that there were not *originally* filed claims that would represent the inventions that are now claimed; however, applicant is reminded of 37 CFR 1.142(b) and MPEP § 821.03. Since applicant has received an action on the merits for the *originally* presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.
- 9. Since the above-mentioned amendment appears to be a *bona fide* attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in

order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.

- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.
- 11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D. May 1, 2003

MAURIE GARCIA BAKER PH.D PRIMARY EXAMINER